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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,238	10/12/2005	Marco Frentsch	GULDE-0057	7138

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,238	FRENTSCH ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 01/30/2008, has been entered.
Claims 1-12 have been amended.
Claims 13-14 have been added.

Claims 1-14 are pending.

2. Given applicant's amended and added claims, filed 01/30/2008, which sets forth two additional Groups, the following Restriction is set forth.

Again, as noted previously with respect to the election of species has been set forth herein, it was noted that the claims appear indefinite under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as they do not recite clear and definitive method steps and appear to be incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Again, applicant is invited to review the claims carefully and consider amending the claims to recite positive steps and ingredients to accomplish the claimed methods.

For example, the recitation of "detecting the expression of CD154" in the absence of clear positive steps and ingredients to accomplish the claimed methods in the claims and in view of the elected species of anti-CD40 antibodies, wherein the elected methods are directed towards detecting the expression of the ligand of CD40, namely CD154/CD40 ligand/CD40L.

For example, the nature and parameters with respect to the recitation of "characterized" is that the nature or parameters of the claimed "characterization" is not defined by the claims and the specification does not provide a standard for ascertaining the requisite degree or direction and, in turn, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention or the parameters by which to determine said metes and bounds.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-9, 11-12, in part, drawn to detecting the expression of CD154.

Group II, claim 1-7, 10-12, drawn to isolating CD154-expressing T lymphocytes.

Group III, claim 13, drawn to antigen-specific T lymphocytes

Group IV, claim 14, drawn to a method of treatment by administering antigen-specific T lymphocytes.

The inventions listed as Groups I-VII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

It is noted that Assenmacher et al. (WO 99/58977) (1449; #002) teach detecting and selecting / isolating antigen-specific T cells based upon CD154-/ CD40L-specific antibodies and employing said enriched antigen-specific T cells (see entire document, including Effector Cell Populations on pages 26-29, Cell Analysis on pages 36-39, Diagnostic Methods for Detecting Antigen-Specific T Cells on pages 39—40 and Methods of Treatment Using Enriched Antigen-Specific T Cells on pages 40-42).

Also, Berner et al. (Ann Rheum Dis 59: 190-195, 2000) (1449; #003) teach detecting and isolating antigen-specific T cells from patients with rheumatoid arthritis (See entire document, including Abstract and Conclusions on page 190; Methods, Results and Discussion).

The invention as well as the species do not provide a contribution over the prior art in that the special technical feature of employing CD154-specific/ CD40L-specific reagents / inhibitors, such as CD40L-specific antibodies have been employed in the detection and isolation of antigen-specific T cells, including their use for diagnostics and therapy. Also, Assenmacher et al. and Berner et al. teach the isolation of antigen-specific T cells, including CD154-/CD40L-expressing T cells.

Additionally, the claimed methods of detection, isolation and treatment methods rely upon different ingredients, process steps and endpoint which are not coextensive and which do not share the same technical feature

In turn, the ingredients for the methods, including the CD40/CD154 system inhibitors, differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered patentable distinct. Further, these molecules do not share a substantial structural feature essential to a common utility do not have common structure to a common utility.

Further, the diseases differ in etiologies and therapeutic endpoints.

Thus the technical feature of employing CD40L-specific reagents in detecting, isolating and using antigen-specific T cells was not special and the Groups are not so linked under PCT Rule 13.2.

Additionally, the claimed methods rely upon different ingredients, process steps and endpoint which are not coextensive and which do not share the same technical feature.

4. In addition to electing a Group from above,
this application contains claims directed to more than one species of the generic invention.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

(A) This application contains claims directed to the following patentably distinct species of the claimed inventions I / II : wherein the methods are directed towards:
(1) methods for detection,
(2) methods for isolation,
(3) methods for detection and isolation,
(4) methods for detection and use in therapies,
(5) methods for isolation and use in therapies, OR
(6) methods for detection, isolation and use in therapies.

(B) In addition to electing a species from (A) above,
This application contains claims directed to the following patentably distinct species of the claimed invention of Group I / II : wherein the methods rely upon a CD40/CD154 system inhibitor selected from those recited in claim 4-7 and those disclosed on pages 13-15 of the instant specification.

If appropriate to either methods of detecting or methods of isolating in Groups I / II;
applicant is required to elect a particular species of a CD40/CD1254 system inhibitor (e.g., anti-CD40 antibody, brefeldin A, etc.).

(C) In addition to electing a species from (A) and (B) above,
This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the detection of CD154 in Group I is
(1) intracellular or
(2) extracellular.

(D) In addition to electing a species from (A), (B) and (C) above,
This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the detection of CD154 in Group I is in/on
(1) fixed cells or
(2) vital cells.

(E) In addition to electing a species from (A), (B), (C) and/or (D) as appropriate above,
This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the detection or isolation of CD154 in Groups I / II is
(1) $CD4^+$ T lymphocytes or
(2) $CD8^+$ T lymphocytes.

In addition, applicant should indicate whether the $CD4^+$ / $CD8^+$ T lymphocytes are inflammatory, anti-inflammatory, regulatory or suppressive T lymphocytes.

5. If Group IV is elected from above,
this application contains claims directed to more than one species of the generic invention.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

This application contains claims directed to the following patentably distinct species of the claimed invention IV: wherein the methods are directed towards:

This application contains claims directed to the following patentably distinct species of the claimed invention: wherein the use in cellular therapy is selected form the infectious, allergic, inflammatory, malignant and autoimmune diseases recited in claim 12 or disclosed on page 16 of the instant specification.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

It is noted that Assenmacher et al. (WO 99/58977) (1449; #002) teach detecting and selecting / isolating antigen-specific T cells based upon CD154-/ CD40L-specific antibodies and employing said enriched antigen-specific T cells (see entire document, including Effector Cell Populations on pages 26-29, Cell Analysis on pages 36-39, Diagnostic Methods for Detecting Antigen-Specific T Cells on pages 39—40 and Methods of Treatment Using Enriched Antigen-Specific T Cells on pages 40-42).

Also, Berner et al. (Ann Rheum Dis 59: 190-195, 2000) (1449; #003) teach detecting and isolating antigen-specific T cells from patients with rheumatoid arthritis (See entire document, including Abstract and Conclusions on page 190; Methods, Results and Discussion).

The invention as well as the species do not provide a contribution over the prior art in that the special technical feature of employing CD154-specific/ CD40L-specific reagents / inhibitors, such as CD40L-specific antibodies have been employed in the detection and isolation of antigen-specific T cells, including their use for diagnostics and therapy. Also, Assenmacher et al. and Berner et al. teach the isolation of antigen-specific T cells, including CD154-/CD40L-expressing T cells.

The invention as well as the species do not provide a contribution over the prior art in that the special technical feature of employing CD154-specific/ CD40L-specific reagents/inhibitors, such as CD40L-specific antibodies have been employed in the detection and isolation of antigen-specific T cells, including their use for diagnostics and therapy.

Further, the species listed above do not relate to a single general inventive concept in that the species lack the same or corresponding special technical features for the following reasons.

For example, the claimed methods of detection, isolation and treatment rely upon different ingredients, process steps and endpoints which are not coextensive and which do not share the same technical feature.

In turn, the ingredients for the methods, including the CD40/CD154 system inhibitors, differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered patentable distinct. Further, these molecules do not share a substantial structural feature essential to a common utility do not have common structure to a common utility.

Further, the diseases differ in etiologies and therapeutic endpoints.

Thus the technical feature of employing CD40L-specific reagents in detecting, isolating and using antigen-specific T cells was not special and the species are not so linked under PCT Rule 13.2.

7. Applicant is required, in reply to this Office Action, to elect a single species as it reads on each of species indicated above as it reads on the elected Group to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878 until January 3, 2007.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/

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